

VA Quality Enhancement Research Initiative (QUERI)

Everything You Need to Know
About VA Non-research
Protocols!

QUERI National Program Office
Office of Research & Development





Using Data & Information Systems in Partnered Research Cyberseminar Series

*Presentations from the field focusing on VA data use
in quality improvement and operations-research partnerships.*

Sessions cover...

- Use of VA data and information systems in QUERI Projects and Partnered Evaluation Initiatives
- Operational data resources and QI-related data
- Challenges in using and managing multiple data sources
- VA resources to support data use
- Experiences working within operations/research partnerships



Where can I
download a
copy of the
slides?

VA HSR&D

CYBERSEMINARS



SAMPLE EMAIL

A Practical Approach to Working with VA-Purchased Community Care Data

Thursday, October 13, 2022

2:00 PM | (UTC-04:00) Eastern Time (US & Canada) | 1 hr

Please download today's slides

~~Please click here for today's live captions~~

Join webinar

More ways to join:

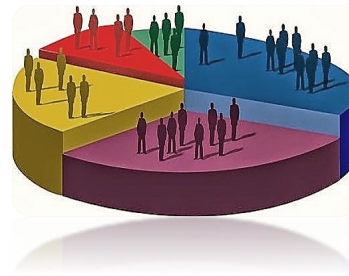
Join from the webinar link

<https://veteransaffairs.webex.com/veteransaffairs/j.php?>

Poll #1:

*What is your primary **role** in projects using VA data?*

- Investigator, PI, Co-I
- Statistician, methodologist, biostatistician
- Data manager, analyst, or programmer
- Project coordinator
- Other – please describe via the chat function



Poll #2:

How many years of experience working with VA data?

- None – I'm brand new to this!
- One year or less
- More than 1, less than 3 years
- At least 3, less than 7 years
- At least 7, less than 10 years
- 10 years or more

VA Quality Enhancement Research Initiative (QUERI)

Everything You Need to Know
About VA Non-research
Protocols!

QUERI National Program Office
Office of Research & Development



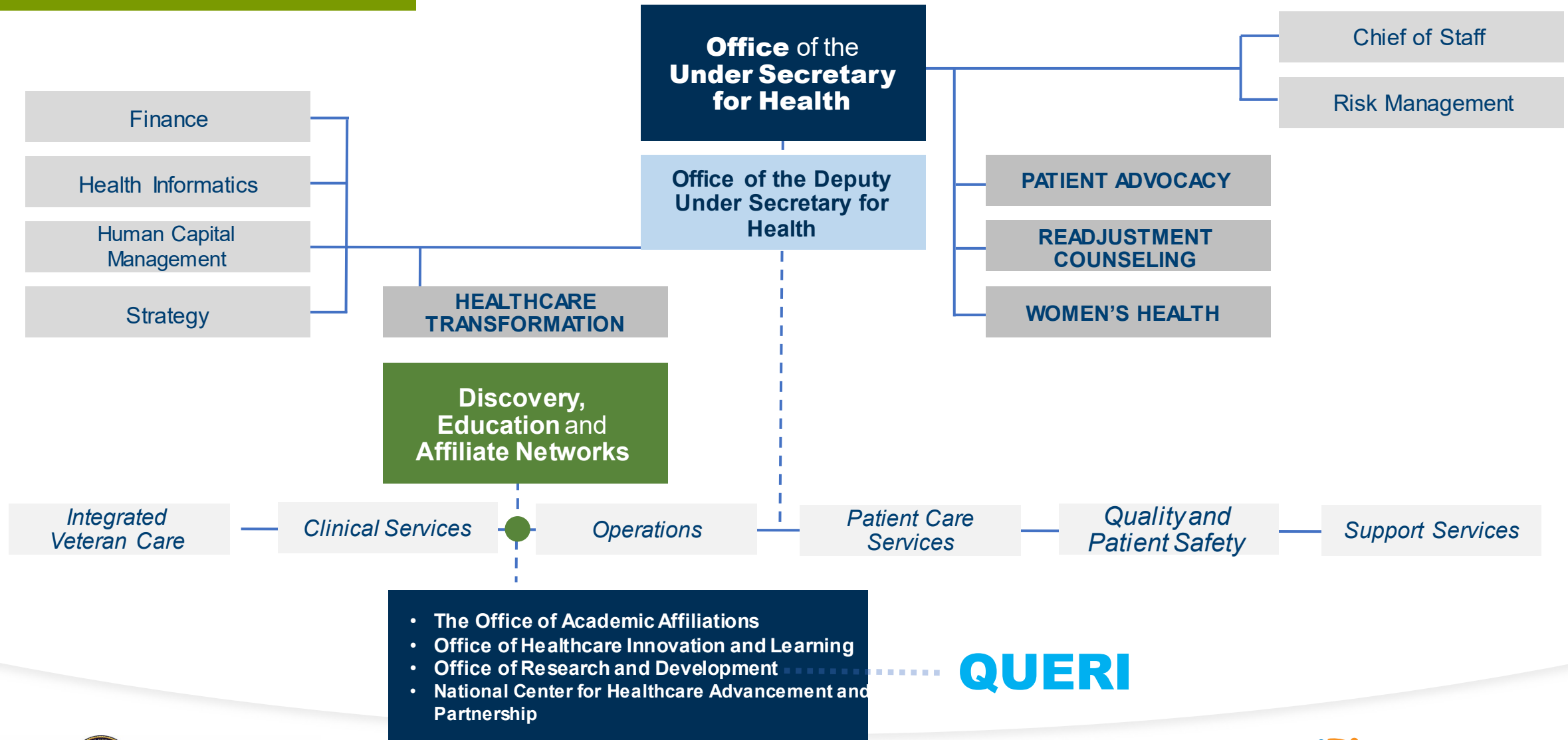
U.S. Department of Veterans Affairs
Veterans Health Administration
Office of Research & Development



Agenda

- **Introductions**
 - Amy Kilbourne, PhD, MPH
- **Key Concepts in Distinguishing Non-Research vs. Research**
 - C. Karen Jeans, PhD, CCRN, CIP
- **VA Electronic Determination Aid (VAEDA)**
 - Molly Klote MD, CIP and Angela Foster
- **QUERI Non-research Examples**
 - Amy Kilbourne, PhD, MPH; Kara Beck, PhD; Melissa Braganza, MPH
- **Questions**

ORD/QUERI under DEAN



Introductions



Molly Klote
Deputy Chief
Research and
Development
Officer for
Enterprise Support



C. Karen Jeans
Director of
Regulatory
Affairs, Office of
Research
Protections,
Policy, and
Education
(ORPP&E)



**Angela
Foster**
Program
Manager,
ORPP&E



Amy Kilbourne
Director, Quality
Enhancement
Research Initiative
(QUERI)



Kara Beck
Program Manager,
QUERI



Melissa Braganza
Deputy Director,
QUERI

Key Concepts in Distinguishing Non-Research vs. Research

C. Karen Jeans, PhD, CCRN, CIP



VA Quality Enhancement Research Initiative
EVIDENCE INTO PRACTICE

Definition of “Research”

VHA Directive 1200.05(2), Paragraph 3. cc.:

cc: “Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this directive, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. Clinical investigations, including clinical investigations as defined under FDA regulations in 21 CFR 50.3, 312.3(b), and 812.3(h), are considered research for purposes of this directive. . . .”

Source: VHA Directive 1200.05(2): Requirements for the Protection of Human Subjects in Research (January 7, 2019; amended January 8, 2021).

Definition of “Research”: Key Phrases


VHA Directive 1200.05(2), Paragraph 3. cc.:

cc: “Research means a **systematic investigation**, including research development, testing and evaluation, **designed to develop or contribute to generalizable knowledge**. Activities that meet this definition constitute research for purposes of this directive, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. Clinical investigations, including clinical investigations as defined under FDA regulations in 21 CFR 50.3, 312.3(b), and 812.3(h), are considered research for purposes of this directive. . . .”

Source: VHA Directive 1200.05(2): Requirements for the Protection of Human Subjects in Research (January 7, 2019; amended January 8, 2021).

Key Phrases: Simplifying the Words

- Systematic investigation:
 - An activity that is planned in advance and that uses data collection and analysis to answer a question. Although research must include systematic investigation, non-research operations activities also include systematic investigation to ensure reliable outcomes. Systematic investigation does not, in and of itself, define research.
 - Source: VHA Program Guide 1200.21, Paragraph 4.e.
- Generalizable knowledge:
 - Information that expands the knowledge base of a scientific discipline or other scholarly field of study. Systematic investigations designed to develop or contribute to generalizable knowledge constitute research.
 - Source: VHA Program Guide 1200.21, Paragraph 4.a.

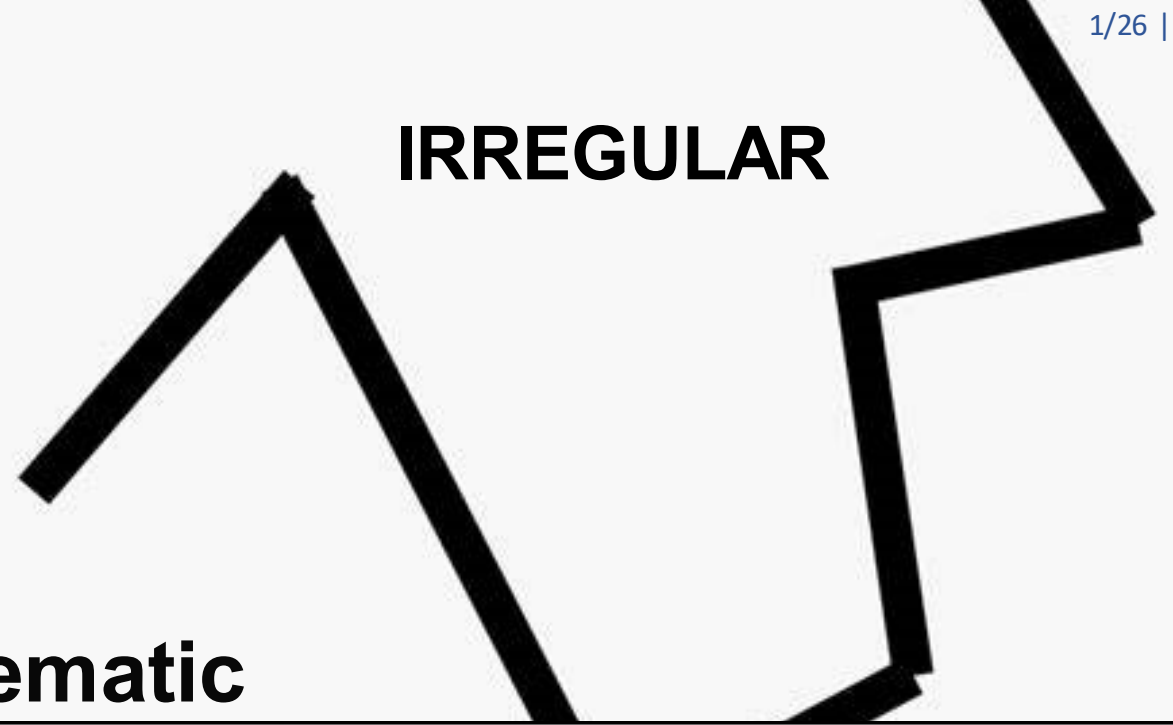
A background image showing a group of business professionals in a meeting. Several hands are visible, pointing at and writing on a large sheet of paper spread out on a table. The scene is dimly lit, focusing on the activity of the meeting.

What is Meant by a Nonsystematic Activity?

DISORGANIZED



IRREGULAR



**Nonsystematic
Adjectives**



UNPLANNED



HIT OR MISS

Non-Systematic Activity – Traveling Without a Plan



What Are Examples of Non-Generalizable Activities?

- Biographies
- Oral histories that are designed solely to create a record of specific historical events
- Service or course evaluations, unless they can be generalized to other individuals
- Case reports of a single patient, two patients, or three patients is not generalizable

Key Characteristics of Non-Research Activities: [ORD Program Guide 1200.21](#): VHA Operations Activities That May Constitute Research

- **Issued by ORD on January 9, 2019 that includes criteria to assist in determining whether a VHA operations activity constitutes research.**
 - Replacement for VHA Handbook 1058.05 “VHA Operations Activities that May Constitute Research,” dated October 28, 2011.
 - Establishes procedures for verifying and documenting the non-research status of certain operations activities prior to publication of findings outside the Department of Veterans Affairs
- **Primary purpose of quality assessment and quality improvement for internal VA purposes.**
 - The activity is designed and implemented for internal VA operational purposes (i.e., its findings are intended to be used by VA or by entities responsible for overseeing VA).
- **Not designed for generalizability beyond VA.**
 - The activity is not designed to produce information that expands the knowledge base of a scientific discipline (or other scholarly field).
 - However, this does not mean that a research activity done solely within VA is not research if it is only conducted within VA.

Examples of Non-Research Operations Activities from ORD Program Guide 1200.21

Quality assessment and quality improvement activities designed for internal VA purposes, including routine data collection and analysis for operational monitoring, evaluation, and program improvement purposes.

- VHA system redesign activities, patient satisfaction surveys, case management and care coordination, policy and guideline development and related evaluation activities
- Competence or qualification reviews of VA employees and health care professionals, performance evaluations; peer review; training and education; accreditation

Examples:

- VA All Employee Survey (AES), Voice of VA Survey
- Cardiac Assessment Reporting and Tracking System (CART)
- External Peer Review Program (EPRP), RAPID
- Home and Community Based Quality Care Initiative
- Inpatient Evaluation Center (IPEC)
- Mental Health Program Evaluation Centers (e.g., SMITREC)
- VA Surgical Quality Improvement Program (VASQIP)
- VHA Quality Improvement Initiative (VQuIP)

Activities that are Research & Require VA R&D Committee Approval and Any Applicable Committee or Subcommittee

- Any activity whose conceptualization, plan, or implementation is **supplemented or modified** in order to produce information expanding the knowledge base of a scientific discipline or scholarly field of study because it is a systematic investigation designed to develop or contributed to generalizable knowledge
- **Modifying or adding to** an existing non-research activity to produce information expanding the knowledge base of a scientific discipline or scholarly field of study as a systematic investigation designed to develop or contribute to generalizable knowledge
- Analyzing non-research data in a **different way** or combining datasets to produce information expanding the knowledge base of a scientific discipline or scholarly field of study when the activity is a systematic investigation designed to develop or contribute to generalizable knowledge

Identifying Research Activities

The following activities **ARE ALWAYS** Research:

- Activities funded or otherwise supported **as research** by the Office of Research & Development (ORD)
- Clinical investigations as defined under Food and Drug Administration (FDA) regulations

The following activities **ARE ALMOST ALWAYS** Research:

Activities using:

- Double blind interventions
- Placebo controls
- Prospective patient-level randomization to clinical interventions not tailored to individual patient benefit

True or False:

Only an IRB can make determinations as to whether an activity is a research or non-research activity.

True or False:

Only an IRB can make determinations as to whether an activity is a research or non-research activity.

FALSE

VA Electronic Determination Aid (VAEDA)

Molly Klote MD, CIP and Angela Foster



VA Quality Enhancement Research Initiative
EVIDENCE INTO PRACTICE

What is VAEDA?

The **VA Electronic Determination Aid (VAEDA)** is a decision support tool created to:

- **Reduce** variability in regulatory preliminary determinations for proposed research, quality improvement, program evaluation, and innovation projects.
- **Decrease** administrative burden on research offices and IRB members.

The VAEDA tool intends to harmonize and standardize project (research/not research) classifications for all VA facilities.

NOTE: Research studies that are known to need an IRB review (clinical trial) or involve animals (IACUC review) do not need to go through the VAEDA process.

How does VAEDA work?

- Fully launched and available in all VAMCs as of September 2022, VAEDA is the validated enterprise solution for research determinations.
- VAEDA helps the project owner understand where a project should be routed for approval, since research offices and IRBs/RDCs have no authority to approve anything that is not research.
 - Project leaders can answer questions regarding their proposed project, and the VAEDA tool will, based on the logic questions answered, produce a preliminary determination
 - Preliminary determinations are intended to be provided to an approving authority (e.g., research into VAIRRS, not research to local process) to complete a final determination and move through the approval process.
- We need **Quality Management** to identify where **not research** determinations should be routed. Currently, >10,000 determination applications per year are routed to IRB chairs and >6,000 are determined to be not research

VAEDA Statistics

How many total determinations – **797**

How many not research determinations – **428**

How many research determinations – **385**

How many exempt determinations – **138**

Estimated total time saved: **> 2,000 person hours**

Estimated frustration saved: **PRICELESS!**

LIVE DEMONSTRATION



U.S. Department of Veterans Affairs
Veterans Health Administration
Office of Research & Development



Where can I find more information on VAEDA?

- Website Links
 - **VAEDA Tool:** <https://vhacdwdwhvda01.vha.med.va.gov/vaeda/home#/>
 - **VAEDA Site Admin Request Form:** <https://forms.office.com/g/FXT4g6tYVr>
 - **VAEDA Homepage:** <https://www.research.va.gov/programs/orppe/vaeda.cfm>
- VA Electronic Determination Aid (VAEDA) Cyberseminar Overview:
https://www.research.va.gov/programs/orppe/education/webinars/session_archive.cfm?RecordID=206910&Date09212022

QUERI Non-research Examples

Amy Kilbourne, PhD, MPH

Kara Beck, PhD

Melissa Braganza, MPH



QUERI VA Quality Enhancement Research Initiative
EVIDENCE INTO PRACTICE

QUERI Non-Research Project Status

- QUERI projects are non-research projects because of the **funding source** (medical administration, or 0160 funds) and their focus on **improvement** within VA.
- Protocols involving data collection are non-research if the **data are fed back to providers or operations leaders** to directly improve care and/or other VA processes. The activity does not meet the definition of research.
- In situations when a QUERI project wants to collect additional data above and beyond what is needed for informing improvement within VA, a determination should be sought as to whether that part of the project's activities constitute research.

QUERI Projects and “Extra Data”

- In situations when a QUERI project wants to collect additional data beyond what is needed for informing improvement within VA, then a determination should be sought as to whether the project’s activities constitute research.
 - In Program Guide 1200.21, this is called collecting “extra” data for systematic investigation to produce information that expands the knowledge base of a scientific discipline (or other scholarly field of study).
 - In contrast, data involving non-research activities are directly fed back to providers or operations leaders to improve processes in the VA.
- However, a research protocol involving extra data or other creation of generalizable knowledge can be “piggy-backed” on top of a QUERI non-research activity

Examples of QUERI Non-research Protocols

Maintaining Implementation through Dynamic Adaptations (MIDAS): protocol for a cluster-randomized trial of implementation strategies to optimize and sustain use of evidence-based practices for VHA patients

Hybrid Type 3 implementation trial evaluating impact of audit & feedback alone vs. audit & feedback plus ongoing team-based quality improvement support (LEAP) to improve uptake of 3 EBPs

ClinicalTrials.gov: [NCT05065502](https://clinicaltrials.gov/ct2/show/study/NCT05065502)

Getting to implementation: a protocol for a Hybrid 3 stepped wedge cluster randomized evaluation of using data-driven implementation strategies to improve cirrhosis care for Veterans

ClinicalTrials.gov: [NCT04178096](https://clinicaltrials.gov/ct2/show/study/NCT04178096)

More Examples of QUERI Non-research Protocols

Provision of peer specialist services in VA patient aligned care teams: protocol for testing a cluster randomized implementation trial (Hybrid Type 3)

ClinicalTrials.gov: [NCT02732600](https://clinicaltrials.gov/ct2/show/study/NCT02732600)

Comparing two implementation strategies for implementing and sustaining a case management practice serving homeless-experienced veterans: a protocol for a type 3 hybrid cluster-randomized trial (Non-research determined per letter and MOU from national program office)

Clinicaltrials.gov: [NCT05312229](https://clinicaltrials.gov/ct2/show/study/NCT05312229)

- Implementation and evaluation of the VA DPP clinical demonstration: protocol for a multi-site non-randomized hybrid effectiveness-implementation type III trial
 - DPP intervention rolled out by the national program office (non-research)
 - Patient, provider outcomes data ascertainment (research component)
- Enhancing Mental and Physical Health of Women through Engagement and Retention (EMPOWER)
 - Compare in-person, peer-led, or virtual Diabetes Prevention Program for women Veterans
 - Facilitating CVD risk screening and risk reduction for women Veterans
 - Tailored mental health collaborative care for women Veterans

All three involved implementation of evidence-based practices, but ascertained extra data on patient, provider, and organizational factors to understand implementation impacts

Clinicaltrials.gov: [NCT02991534](#), [NCT02950961](#)

QUERI Non-Research Letter

- Describes how the project (and data collected during the course of the project) is designed for internal quality improvement purposes, as part of the agreed-upon protocol established with the VA operations partner
- Signed by the VHA operations partner affiliated with the QUERI project
- QUERI Central Office developed a template, which is posted on the [QUERI SharePoint site](#)
- If you are not a QUERI investigator/staff and would like a copy of the template, please email QUERI Central Office (vacoqueri@va.gov)

| DEPARTMENT OF VETERANS AFFAIRS | Memorandum |
|---|------------|
| Date: | |
| From: Operational Leader Authorized to provide Non-Research Documentation Project | |
| Sub: Project title | |
| To: Project PI | |
| <p>1. The purpose of this letter is to confirm that the VA Quality Enhancement Research Initiative (QUERI) project entitled "Project title" meets the criteria for classification as non-research. This project is being conducted at the VA Medical Center and is led by Project PI. The implementation/evaluation of (describe project) is designed to inform quality improvement efforts, as part of the agreed-upon protocol established with QUERI and (operations partner).</p> <p>2. The purpose of this project is to support internal implementation and evaluation efforts to (describe aims of project). The project will involve use of secondary and (if applicable) primary VA data collected using assessments that are part of routine care and/or clinical management. This project will be collecting information that is designed for quality improvement initiatives, as described in Program Guide 1200.21, for the purposes of program implementation/evaluation.</p> <p>3. These activities are designed and implemented for internal VA purposes and findings are intended to be used to better inform care in the VA. This project is not designed to inform activities beyond VA, produce information that expands the knowledge base of a scientific discipline or other scholarly field, and does not involve collecting additional data or performing analyses that are not needed for the purposes of this internal implementation.</p> | |
| Signature and title of VA operational leader from program office authorized to sign off on non-research projects | |

Points of Contact

- For **QUERI-funded activities**, contact **Kara Beck**, QUERI Program Manager, at kara.beck@va.gov.
- For **ORD projects**, contact the **Scientific Program Manager** for the specific project with questions.
- For **ORD regulatory policy questions**, contact **VHA CO ORD Regulatory** VHACOORDRegulatory@va.gov with regulatory questions.

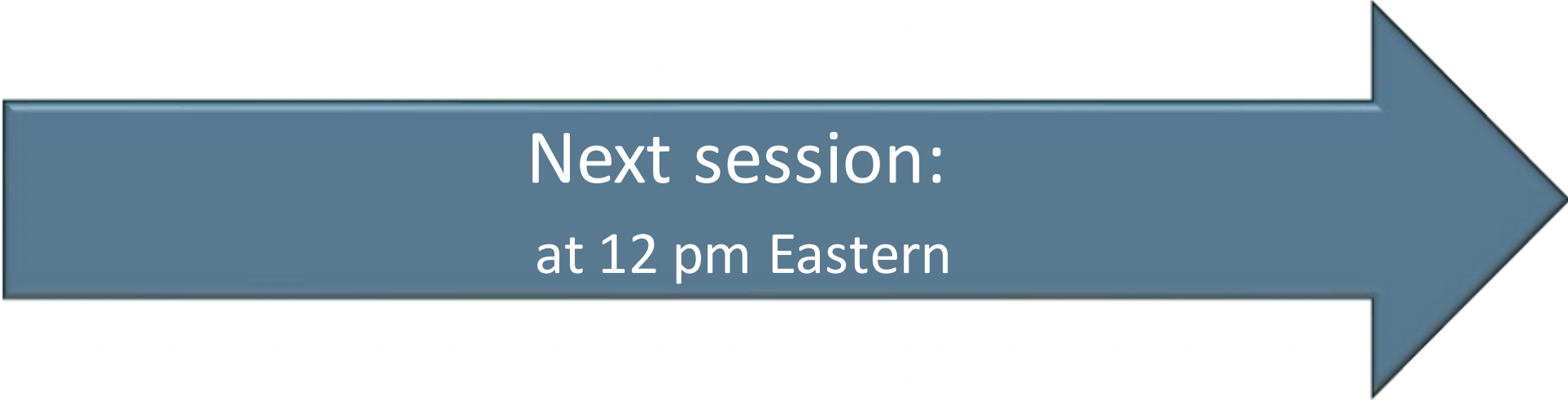


Questions?

We are happy to answer questions! Please submit questions using the chat.



Using Data & Information Systems in Partnered Research Cyberseminar Series



Next session:
at 12 pm Eastern

QUERI Advancing Diversity in Implementation Leadership
(ADIL): Examples from the Field on Optimizing and Leveraging
VA Leadership Opportunities



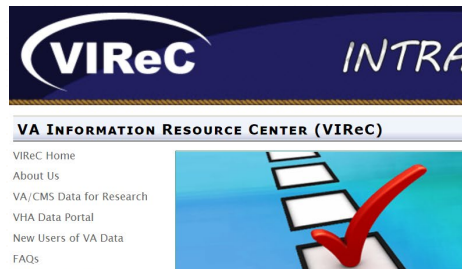


VIReC Partnered Research **BONUS SLIDES**

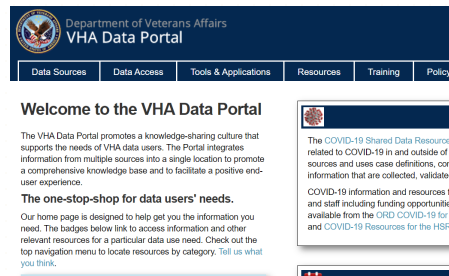


Resources for VA Data Users

Select image to visit page



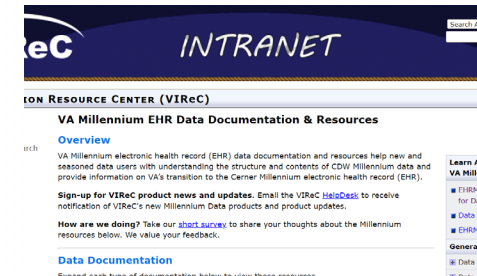
VA Information Resource Center (VIREC) (VA Intranet)



VHA Data Portal (VA Intranet)



VIREC Cyberseminars



VA Millennium EHR Data Documentation (VA Intranet)

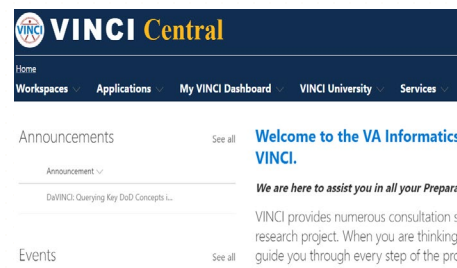


Resource Center (VIREC) is funded by the VA Research & Development Service (HSR&D) to use data effectively for research and training programs, and to foster communication between data users and the VA healthcare community.

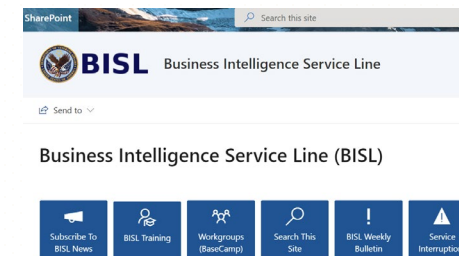
Visit Our Website
www.virec.research.va.gov

Visit the VHA Data Portal

Quick Guide: Resources for Using VA Data (VA Intranet)



VA Informatics and Computing Infrastructure (VINCI) (VA Intranet)



BISL/CDW (VA Intranet)



Health Economics Resource Center (HERC) (VA Intranet)



Questions about using VA Data?

HSRData Listserv

- Community knowledge sharing
- ~1,400 VA data users
- Researchers, operations, data stewards, managers
- Subscribe by visiting
vaww.virec.research.va.gov/Support/HSRData-L.htm (VA Intranet)

VIReC HelpDesk

- Individualized support
- Request Form:
varedcap.rcp.vaec.va.gov/redcap/surveys/?s=KXMEN77LXK (VA Intranet)

